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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,918	12/13/2005	John E. Hansen	13323-105003	5673
65989	7590	08/07/2008		
KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003			EXAMINER HAND, MELANIE JO	
			ART UNIT 3761	PAPER NUMBER
			NOTIFICATION DATE 08/07/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/538,918	Applicant(s) HANSEN ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,85,88,91-106,118-120 and 130-164 is/are pending in the application.
- 4a) Of the above claim(s) 91-106,118-120 and 130-164 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,85 and 88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/15/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed April 18, 2008 have been fully considered but they are not persuasive.
2. With respect to arguments regarding claims 1, 84, 86, 87, 91-94, 107, 116 and 117: Applicant argues that Hahn does not teach or suggest a swab and a support fixed to the swab and relies upon the disclosure by Hahn of a swab and a stick cited by examiner in Col. 17, line 46 as support for the argument. Since it is clear applicant has misunderstood examiner's position, it will be clarified here. The stick disclosed by Hahn is the "mode of delivery" of the "vehicle", which is the collagen in a solid or semisolid form, which can be considered herein to be a swab since all that a swab is a piece of material of any particular desired shape. (Col. 17, lines 1-3, 14, 15, 33-35, 39-41, 44-46) As to applicant's argument that Hahn does not teach a swab comprising natural or synthetic material comprising gelatin or collagen, again, the "vehicle" comprising the collagen is the carrier for the formulation disclosed by Hahn and is delivered via a stick support. Therefore, the solid or semisolid configuration of the collagen defines a swab that comprises the collagen (which can be either natural or synthetic) carrier with the formulation therein, thus certainly meeting the limitation of a swab which is a natural or synthetic absorbent material comprising collagen particles. Applicant's argument that one must select from a vast number of vehicles to arrive at a collagen swab is not persuasive because the vehicles are grouped by their respective states at room temperature (.e.g. a volatile organic solvent, lipid based materials and collagen or gelatin). Hahn discloses that they are all well known in the art and thus one of ordinary skill in the art would not have to choose from an extensive list of vehicles; it is examiner's position that one of ordinary skill in the art would

choose a general type of vehicle based upon consistency and appearance as desired for the particular use or application, from which a vehicle is chosen from only a very small list of examples explicitly disclosed by Hahn. As to applicant's argument that Hahn does not disclose applying the collagen or gelatine material and that those materials are instead used to apply alcohols, it is noted that the features upon which applicant relies (i.e., the application of a particular material) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

3. With respect to arguments regarding claim 91: Applicant additionally argues with respect to claim 91 that the presence of water and the swab cannot constitute a kit, such a kit is precisely what is claimed by applicant. Though it is true that claim 91 contains the open-ended term "comprising", not other elements of the kit are claimed. Thus if applicant is arguing that a kit cannot be a swab and water, then applicant's kit cannot be a kit either by applicant's own argument.

4. With respect to arguments regarding claims 93,95: Applicant's arguments with regard to dependent claim 93 have been fully considered but are not persuasive, as applicant's arguments depend entirely on arguments regarding the rejection of claim 1, which have been addressed *supra*. As to applicant's argument that no skin cells are transferred, it is noted that the features upon which applicant relies (i.e., that skin cells be transferred upon completion of the step of transferring the target from the swab to a first transfer medium) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, cells are nearly always transferred to an applicator as a result of the swiping motion of the applicator on a skin or tissue surface.

5. With respect to arguments entitled "Additional Comments": First, applicant argues that documentary evidence must be provided for examiner's statement that "collagen is protein-based and thus of natural origin". This statement does not require evidence for two reasons: (1) Hahn discloses verbatim that collagen is protein-based and applicant acknowledges this disclosure by citing it on page 10 of the Remarks; and (2) it is a universally known fact that proteins are created by natural processes-they are the building blocks for the creation of nearly everything found in nature. Therefore, applicant need only look at every plant and human surrounding the applicant at any particular time as documentary evidence. Second, applicant requires documentary evidence that ethanol is an organic buffer. Ethanol is an organic compound that is fully capable of being, and often is, used as buffer solution, i.e. the other component aside from the buffering agent that, together with the agent, constitutes the buffer. Thus, since the ethanol is fully capable of acting as an organic buffer, this statement by examiner also requires no documentary evidence. Last, the statement that "microfibrillar collagen is a form of collagen" is also a universally understood physical fact that therefore requires no documentary evidence. In fact, simply referring to "microfibrillar collagen" in the disclosure and reciting microfibrillar collagen as an appropriate material for the claimed collagen swab is an acknowledgment in itself by applicant that this statement regarding microfibrillar collagen is physical fact and is universally understood. Examiner cites herein guidance from MPEP §2144.02 as to when it is acceptable for an examiner to take official notice as a courtesy to the applicant: "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and

unquestionable demonstration as to defy dispute” (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).” (MPEP §2144.02)

Election/Restrictions

6. Newly submitted claims 137-164 and newly amended claims 91-106 and 118-120 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

a. With regard to amended claims 91-106 and 118-120: Applicant amended independent kit claim 91 to now recite a device for sampling or collecting comprising a “swab comprising gelatine or collagen”, whereas claim 91 previously recited a device according to now cancelled claim 84, which recited “a swab which is a natural or synthetic absorbent material comprising gelatine particles or collagen particles”. The swab recited in now cancelled claim 84 is a different species of the swab and kit now recited in claim 91 because the gelatine or collagen now recited in claim 91 may or may not be in particle form and it is not clear from claim 91 whether the gelatine is specifically natural, specifically synthetic or can be either natural or synthetic. Thus the kit of claim 91 is now drawn to a non-elected invention. Claims 92-94, 96, 98-106 and 118-120 either directly or ultimately depend from claim 91 and are also thus directed to a non-elected invention. With regard to amended claim 95, applicant amended independent method claim 95 to now recite a method comprising the step of swiping the area with a swab comprising gelatine or collagen, whereas claim 95 previously recited a method reciting the same step wherein the swiping step is performed with a device according to claim 1 which comprises “a swab which is a natural or synthetic absorbent material comprising gelatine particles or collagen particles”. The swab recited in claim 1 is a

different species of the swab and kit now recited in claim 95 because the gelatine or collagen now recited in claim 95 may or may not be in particle form and it is not clear from claim 95 whether the gelatine is specifically natural, specifically synthetic or can be either natural or synthetic. Thus, the method of claim 95 would have been grouped with its device in any restriction requirement and the device performing the steps in amended claim 95 is materially different from the device of claim 1. Thus the method of claim 95 is now drawn to a non-elected invention. Claims 96, 99, 100 and 118-120 directly or ultimately depend from claim 95 and are also thus directed to a non-elected invention. With regard to amended claim 97, applicant amended independent method claim 97 to now recite a method comprising the step of making contact between a swab comprising gelatin or collagen and at least a portion of a sample area. Claim 97 previously recited a method reciting the same making contact step wherein the step is performed with a device according to now cancelled claim 84, which recited "a swab which is a natural or synthetic absorbent material comprising gelatine particles or collagen particles". The swab recited in now cancelled claim 84 is a different species of the swab and kit now recited in claim 97 because the gelatine or collagen now recited in claim 91 may or may not be in particle form and it is not clear from claim 97 whether the gelatine is specifically natural, specifically synthetic or can be either natural or synthetic. Thus, the method of claim 97 would have been grouped with the corresponding device in any restriction requirement and the device performing the steps in amended claim 97 is materially different from the device of claim 84. Thus, the method of claim 97 is now drawn to a non-elected invention. Claims 99, 100 and 118-120 directly or ultimately depend from claim 97 and are also thus directed to a non-elected invention.

- b. With regard to newly presented claims 137-164: Each of these claims either directly or ultimately depend from a claim that is constructively non-elected by original presentation for any one of the reasons stated *supra* in paragraph 5a of this action.
7. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 91-106, 118-120 and 137-164 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
8. For clarification, the claims examined in this action are claims 1, 85 and 88.

Information Disclosure Statement

9. The information disclosure statement (IDS) submitted on February 15, 2008 was filed after the mailing date of the non-final action on October 30, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hahn et al (U.S. Patent No. 5,804,203).

With respect to **claim 1**: Hahn teaches a device comprising i) a swab applicator which is a natural or synthetic absorbent material comprising collagen particles; and ii) a support in the form of a stick fixed to said swab by adhering the instant formulation comprising collagen to said stick. With regard to the limitation “for sampling or collecting”, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. (Col. 17, lines 44-54)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 85 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al ('203).

With respect to **claim 85**: Hahn teaches that the swab is collagen-based, however Hahn does not explicitly teach that the collagen is microfibrillar collagen. However, since microfibrillar collagen is a form of collagen that is also suitable for any application that a collagen is suitable for, it would be obvious to one of ordinary skill in the art to modify the article of Hahn such that the collagen is microfibrillar collagen with a reasonable expectation of success to preserve the function of the article. If there is a design need or a market pressure to solve a problem, and there are a finite number of identified, predictable solutions (in this case varieties of collagen or gelatine that can perform the function of sample collection), a person of ordinary skill in the art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007)

With respect to **claim 88**: Hahn also teaches a gelatine-based sponge. With regard to the limitation "the gelatine-based sponge has a water absorption capacity of at least 30 g/g", when the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, a swab comprising a gelatine-based sponge material) except for a property or function (in the present case, the absorption capacity of said gelatine-based sponge material) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render

obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761